

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

Novartis Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419-8300
www.cp.us.novartis.com

Tel 336 632 6000



May 20, 1999

Ms. Carmelita White
Chemical Review Manager
Special Review and Reregistration Division
Office of Pesticide Programs H7504C
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, DC 20460

SUBJECT: PROFENOFOS; STATUS OF WORKER SAFETY
INITIATIVES. (CASE 2540; CHEMICAL 111401)

Dear Ms. White,

This is to inform the EPA of the progress of initiatives that Novartis has started to address worker exposure issues with Curacron® 8E.

Closed System Packaging: Novartis has begun using the new closed system packaging for Curacron 8E 2.5 gallon jugs. Novartis has worked with Bayer and other companies to choose engineering for the closed system that will be an industry standard and thus widely used. The Securalink-G® system has been widely tested and accepted by growers and applicators. This system affords superior performance in reducing exposure to mixer/loaders and handlers. Two brochures for the product are included with this letter.

Worker Safety Studies. In order to demonstrate worker safety with Curacron, Novartis is initiating two studies designed to determine the actual exposure of field workers to Curacron. The first is an animal metabolism study conducted with 14C-profenofos designed to determine the metabolites in urine that will be best biomarkers for this compound. We are on track to initiate this study shortly. Once the appropriate biomarkers have been identified, method development and validation will be conducted. The second study is a field mixer/loader/applicator exposure biomonitoring study involving monitoring of workers using the product. Study personnel will collect urine from workers (mixer/loaders, applicators, flaggers, etc.) who are engaged in the application of Curacron. This study will determine the amounts of profenofos absorbed by the body as a result of actual Curacron use. This study is scheduled to start during the cotton use season of 2000. The study can only be conducted after the appropriate biomarkers and analytical methodology are developed, thus the initiation date of next year. A protocol for the field biomonitoring study is available for Agency review and will be sent upon request.

Although exposure assessments using PHED indicate theoretical risk to be unacceptable, Novartis believes that this is not an accurate representation of Curacron exposure due to the lack of robustness of the closed-system handling data in PHED. This notion is further supported by the fact that there were few adverse effects reports summarized in the epidemiological information in the RED. And since 1996, there have been no other 6(a)(2) reports on mixer/loader or handler exposures. Novartis believes the outcome of the planned exposure study will confirm the safety of Curacron to workers.

Thank you for your assistance. If you have any questions regarding this response, please contact me at (336) 632-2391.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert E.M. Wurz", written in a cursive style.

Robert E.M. Wurz, Ph.D.
Senior Regulatory Manager
Regulatory Affairs

The New Curacron Closed System Offers these Great Benefits

Safety

A one-way, improved dry-disconnect valve means no drips, no spills and reduced exposure. You get safer, accurate chemical transfer each and every time.

Accuracy

Securalink-G lets you dispense less than a full jug to top-off your sprayer load. To reduce the risk of personal exposure or spills, the valve on the jug stays closed until the remaining contents are needed for another load.

Control

A unique valve fitting (Securalink-G) and shutoff lets you control the flow while dispensing. The more you turn the container, the greater the flow rate.

Convenience

The Securalink-G valve comes installed on your Curacron jug from Novartis. This allows Curacron to be delivered in a standard 2 1/2 gallon container that is convenient and familiar to workers.

Good Stewardship

The Securalink-G valve is designed to be disposable after rinsing. Always follow proper procedures for rinsing and disposing of chemical jugs.

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For more information about the Securalink-G system, contact Sotera Systems at 800-796-0614.



Novartis Crop Protection, Inc., Greensboro, NC 27419-8300.

Curacron is a Restricted Use Pesticide.

Important: Always read and follow label instructions before buying or using this product.

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Curacron® and the Novartis logo are trademarks of Novartis.

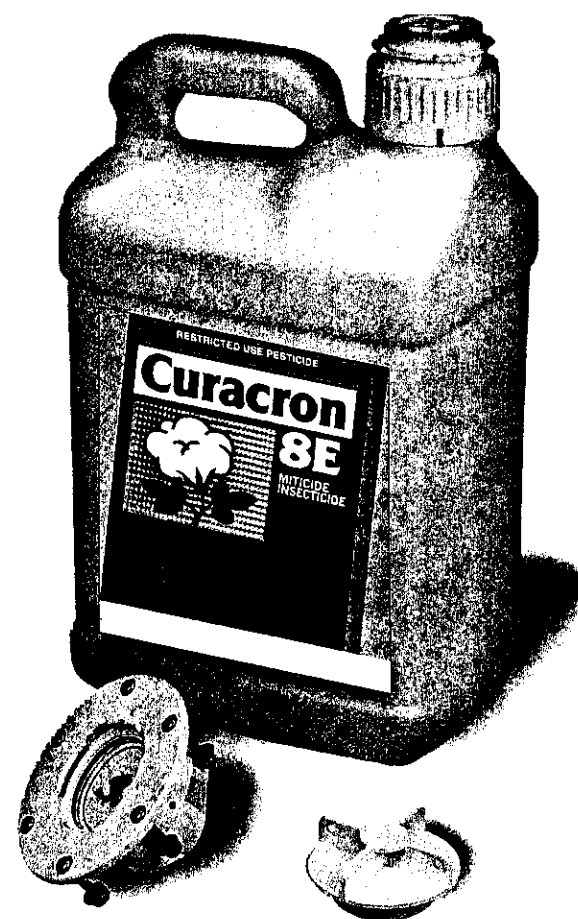
Securalink-G® and Sotera Systems® are trademarks of Sotera Systems.

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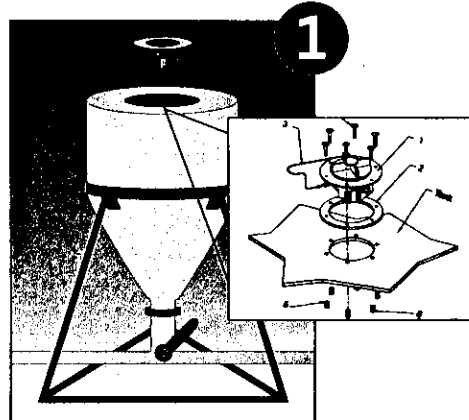
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INTRODUCING... The New Curacron® “Closed Transfer” Handling System



Follow these Simple Steps To Use The New System

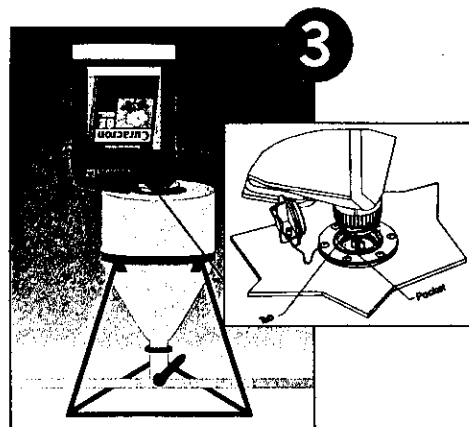
Now Curacron is available in a 2 1/2 gallon "Closed-Transfer" handling system. The Securalink-G® system, designed by Sotera Systems®, uses a standard 2 1/2 gallon container with a permanently installed valve mounted in the container opening. When the Curacron container is connected to the tank adapter permanently mounted on a mix or spray tank, Curacron can be transferred through the closed system accurately and with minimal worker exposure. The 2 1/2 gallon container, once empty, can be probed with a rinsing spear, properly rinsed, then removed from the fitting and disposed of.



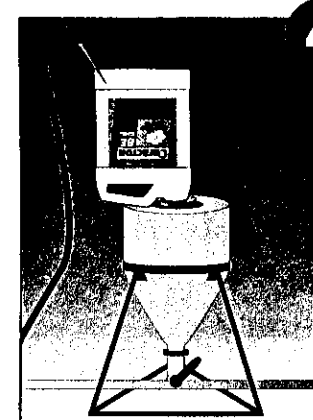
1
Permanently mount the Securalink-G tank adapter to the top of a mixing vessel or tank. (Follow specific Securalink-G installation instructions provided with the tank adapter.)



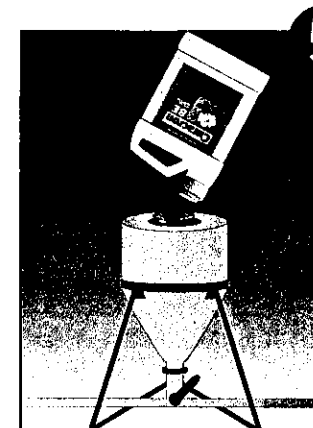
2
Remove the tamper-evident cap from the top of the Curacron jug.



- 3
- Remove the tank adapter lid by rotating it counter-clock-wise and pulling up.
 - Invert jug with Securalink-G valve and align the four tabs of the valve with the four pockets of the tank adapter. **Apply downward pressure to the jug to fully engage the valve.** This is the closed position.
 - To dispense the product, rotate the jug clockwise until the desired flow rate is obtained. **Do not over-rotate the jug.** Maximum rotation is about 45 degrees.
 - To slow or stop dispensing, rotate the jug counter-clock-wise. The flow will stop when the tabs and pockets are aligned.



4
After Curacron is completely dispensed, insert a rinsing spear and properly rinse the Curacron jug.



5
To remove the valve from the tank adapter, align the tabs with the pockets and lift jug straight up and out of the tank adapter. Replace the tank adapter lid to keep the area clean and free of debris.